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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,120	11/29/2004	Masaru Yamakoshi	1516-0126PUS1	3292
2292	7590	05/21/2007		
BIRCH STEWART KOLASCH & BIRCH			EXAMINER	
PO BOX 747			MARTIN, PAUL C	
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
			1657	
			NOTIFICATION DATE	DELIVERY MODE
			05/21/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,120	<b>Applicant(s)</b> YAMAKOSHI ET AL.	
	<b>Examiner</b> Paul C. Martin	<b>Art Unit</b> 1657	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 12-14, 18-20, 27, 28, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14, 18-20, 27, 28, 30 and 31 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-9, 12-14, 18-20, 27, 28, 30 and 31 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

At the outset, the Examiner withdraws the finality of the last action and re-opens prosecution with the current Office Action on the merits.

The rejection of Claim 1 under 35 U.S.C. § 102(b) as being anticipated by Larner *et al.* (US 5,750,348) has been withdrawn due to the Applicant's amendments to the claims filed 04/27/07.

The rejection of Claims 1-5 under 35 U.S.C. § 103(a) as being unpatentable over Larner *et al.* (US 5,750,348) in view of Ashizawa *et al.* (2000) has been withdrawn due to the Applicant's amendments to the claims filed 04/27/07.

The rejection of Claims 1-7, 19, 20, 27 and 28 under 35 U.S.C. § 103(a) as being unpatentable over *Larner et al.* (US 5,750,348) in view of *Ashizawa et al.* (2000) and further in view of *Tazoe et al.* (US 6,309,852) has been withdrawn due to the Applicant's amendments to the claims filed 04/27/07.

The rejection of Claims 1-9, 18-20, 27 and 28 under 35 U.S.C. § 103(a) as being unpatentable over *Larner et al.* (US 5,750,348) in view of *Ashizawa et al.* (2000), *Tazoe et al.* (US 6,309,852) and further in view of *Kozuma et al.* (US 6,046,018) has been withdrawn due to the Applicant's amendments to the claims filed 04/27/07.

### ***Response to Arguments***

Applicant's arguments, see Remarks, filed 04/27/07, with respect to the rejection(s) of claim(s) 1-9, 12-14, 18-20, 27 and 28 under 35 U.S.C. § 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of *Takatsuma et al.* (JPO 2001190299A).

***Claim Rejections - 35 USC § 102***

Claims 1-5, 8, 9, 14, 30 and 31 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Takatsuma *et al.* (JPO 2001190299A).

Takatsuma *et al.* teaches a method for detecting an insulin secretory defect or impaired glucose tolerance in a subject by providing urine samples from a subject, wherein the samples are obtained before and after a glucose load; quantitatively determining the glucose (glucose II-HA) and myo-inositol in the samples using myoinositol dehydrogenase enzymatic cycling method wherein thio-NAD is used as a coenzyme at a concentration of 2mM and determining that the subject has an impaired glucose tolerance (IFG, IGT) or insulin secretory defect (diabetes mellitus) based on the concentration of myo-inositol in the samples being at or higher than a characteristic value, and a method for detecting an insulin secretory defect or impaired glucose tolerance in a subject by providing blood samples from a subject (Pgs. 17 and 18, Paragraph [0113], Pgs. 19 and 20, Paragraphs [0120], [0121] and [0124]).

Takatsuma *et al.* teaches the elimination of glucose using Hexokinase II (ATP hexokinase) prior to determination of myoinositol (PG. 15, Paragraph [0099]).

***Claim Rejections - 35 USC § 103***

Claims 1-9, 14, 18-20, 27, 28, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takatsuma *et al.* (JPO 2001190299A) in view of Tazoe *et al.* (US 6,309,852 B1).

The teachings of Takatsuma *et al.* were discussed above.

Takatsuma *et al.* does not teach wherein ATP-hexokinase and ADP-hexokinase are simultaneously used for the elimination of sugars other than myoinositol in the sample, wherein in the samples ATP is reacted with glucose to form ADP and glucose-6-phosphate (G-6-P) and reacting the ADP to form AMP and G-6-P.

Tazoe teaches that the removal of glucose using hexokinase results in the unfavorable formation of large quantities of ADP (Column 1, Lines 55-67) and that when glucose is eliminated by the use of hexokinase, that unfavorable amounts of ADP are formed (Column 1, Lines 59-67), and further teaches that when the enzyme acting on the analyte also acts on glucose and the reaction catalyzed by the enzyme is subject to influence of the NDP concentration, it is preferred to eliminate glucose using system A in which the enzyme is NDP-dependent hexokinase and the coenzyme is NDP converted to NMP (Column 6, Lines 23-28).

Further, Tazoe *et al.* definitively teaches the elimination of glucose from a reaction through the simultaneous use of NTP-dependent hexokinase to facilitate the reaction of glucose and NTP to glucose-6-phosphate and NDP and the reaction of NDP with NDP-dependent hexokinase to form NMP (Column 5, Lines 14-22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method for quantitatively determining the amount of myo-inositol in urine and blood samples and the use of ATP-hexokinase to remove interfering glucose as taught by Takatsuma *et al.* above with the method of eliminating glucose interference using two kinds of kinase, one of which being ADP-dependent hexokinase as taught by Tazoe *et al.* in order to remove the possible interference of glucose and ADP on the reaction. One of ordinary skill in the art would have been motivated to combine the two methods in order to achieve the dual advantages of removing glucose interference by two overlapping means and simultaneously removing potentially interfering ADP accumulations as taught by Tazoe *et al.* above. There would have been a reasonable expectation of success based upon the fact that both methods use hexokinase and teach eliminating glucose interference in the clinical examination of markers for glucose intolerance or insulin secretion defect markers.

Claims 12 and 13 are free of the art but are objected to as being dependent upon rejected Claims 1 and 2.

No Claims are allowed.

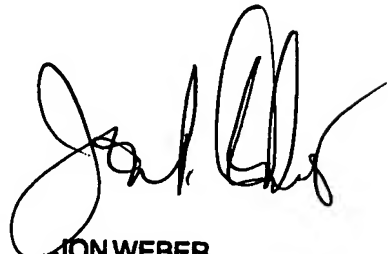
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1657

5/15/07

  
**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**